

001
RECEIVED
CENTRAL FAX CENTER
APR 09 2005

Docket No.: VAS-5041CIP2

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[X] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner Brian E. Pellegrino at Facsimile No 703-872-9306.

Dated: April 7, 2005

Name of Person Certifying:
Printed Name:

Guy Cumberbatch
Guy Cumberbatch

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shannon

) Group Art Unit: 3738

Application No.: 09/997,829

) Examiner: Brian E. Pellegrino

Filing Date: November 29, 2001

For: RADially EXPANDABLE
TUBULAR STENT GRAFTS

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. §41.41

Dear Sir:

Responsive to the Examiner's Answer dated February 9, 2005, Applicant wishes to reply by emphasizing the lack of motivation to combine the two primary references. The main issue on appeal is:

1) Whether claims 103-105, 107, and 113-117 are not patentable under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 5,700,285 to Myers, et al. ("Myers") in view of U.S. Patent No. 4,131,648 to Choi et al. ("Choi").

Applicant again respectfully submits that Myers in combination with Choi does not render the pending claims obvious to one of ordinary skill in the art, primarily because the Examiner has not established a *prima facie* case of obviousness.

BEST AVAILABLE COPY

Application No.: 09/997,829

Filing Date: November 29, 2001

Reply Brief under 37 C.F.R. §41.41 dated April 7, 2005

Responsive to Examiner's Answer dated February 9, 2005

Sole independent claim 103 is reprinted below:

103. (Previously presented) An implantable drug eluting device that has a compressed undeployed diameter and an expanded deployed diameter, the device comprising:

5 a radially expandable stent comprising a generally cylindrical wall surface and having a hollow bore extending longitudinally therethrough, wherein the generally cylindrical wall surface comprises a plurality of lateral openings in the wall surface;

a coating comprising a polymer and a therapeutic substance disposed on the wall surface of the stent; and

10 a tubular outer layer comprising expanded, sintered PTFE tape wound about the outer surface of said stent.

Myers, et al. discloses a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and a tubular covering of porous expanded PTFE film affixed to the
15 stent. There is absolutely no mention of incorporating a therapeutic substance (i.e., a drug) into the intraluminal graft.

Choi discloses generally a polymer formulation in which a "beneficial agent" is incorporated. The polymers exhibit a controlled degree of the erosion in an aqueous environment and thus can be used for making devices and coatings for releasing a beneficial agent as the
20 polymers erode. However, Choi offers no suggestion that a stent or graft can be coated with the polymers disclosed. Importantly, various examples in Choi are given, none of which include a stent or graft, as has been illustrated in the Appeal Brief by reiteration of the examples of Choi:

FIG. 3 - exemplary square shape

FIG. 4 - multilayered structure

25 FIG. 5 - two layers of different polymers having different bioerosion rates

FIG. 6 - bioerodible polymer having a multiplicity of microcapsules

FIG. 7 - a support base layer formed of a breathable impervious material, with a bioerodible solid polymer containing a drug fixed thereto...useful for administering drug to the skin, mucosa or an exposed wound.

Application No.: 09/997,829

Filing Date: November 29, 2001

Reply Brief under 37 C.F.R. §41.41 dated April 7, 2005

Responsive to Examiner's Answer dated February 9, 2005

FIG. 8 a depot implant comprised of a pair of layers and a single layer sandwiched therebetween...after an operation is completed and the patient regains consciousness, an implant containing an analgesic can be implanted into the body to ease pain as it bioerodes

FIGS. 9 and 10 a device having a cylindrical shape and a passageway extended through the center made of a bioerodible polymer for releasing drug within a vagina. The passageway manipulates the amount of drug released by increasing the surface exposed to the fluid of the environment of use. FIG. 10 illustrates a device for insertion into the natural cavities such as the anus 25.

FIGS. 11a and 11b - a device for placement in a human eye including an ocular insert consisting of a bioerodible polymer.

FIG. 12 - a device for releasing a drug within a uterus 36 having a round tube shaped body made of bioerodible polymer that contains a drug.

While the Examiner may be familiar with the pertinent legal standards for obviousness, the Examiner has misapplied these standards in the instant case. The Federal Circuit cases cited by the Examiner in support of this position, in fact, contradict his position. Thus, the Examiner cites the following cases: In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) (The court found there was no suggestion to combine these references to arrive at the claimed invention). In each of these cases, the Federal Circuit reversed the Board of Appeals and found no basis to combine the references at issue; i.e., no *prima facie* case was found.

The standard for combining references has been stated in slightly varying ways, though the following passage from In re Dembiczak (copy attached) is a comprehensive example.

We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in

Application No.: 09/997,829

Filing Date: November 29, 2001

Reply Brief under 37 C.F.R. §41.41 dated April 7, 2005

Responsive to Examiner's Answer dated February 9, 2005

the art, or, in some cases, from the nature of the problem to be solved, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), Para- Ordinance Mfg. v. SGS Imports Intern. Inc., 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," Rouffet, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be *clear and particular*. See, e.g., C.R. Bard, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." In re Dembiczak, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999).

It is interesting that the Examiner quotes the "clear and particular" phrase from In re Dembiczak when, in fact, the court's language completely undermines the Examiner's argument in the instant case. Far from offering any actual evidence "of a suggestion, teaching, or motivation to combine" the cited references, the Examiner ignores the Court's prohibition against using "broad conclusory statements regarding the teaching of multiple references, [that] standing alone, are not 'evidence.'"

For a section 103 obviousness combination, the Federal Circuit recognizes that there may be a) explicit evidence within the references themselves, or b) implicit evidence from "the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." In the present case the Examiner has not identified any explicit suggestion in Choi or Myers to combine the two teachings. Instead, the Examiner admittedly relies on the implicit form of evidence to make the combination.

Specifically, at pp. 6-7 of the Answer, the Examiner states that

stent-grafts are used in vessels, which permit the flow of fluid, whether it is blood, urine or even bile. Choi teaches that the polymer coatings containing drugs are used in aqueous or 'fluid' environments (Col. 28, lines 61-68) and that the device the polymer is used with can permit the drugs to be transported across a vessel, col. 29, lines 24-29. It is well known to one of ordinary skill in the art that blood vessels, ureter, urethra or bile ducts all carry fluid that would be considered an aqueous environment and that stent-grafts are often used to hold open and support these vessels when they are blocked, clogged, or have a reduced flow rate. Someone of ordinary skill in the art would also know what a coating is and would look to the coating art to provide a delivery vehicle for

Application No.: 09/997,829

Filing Date: November 29, 2001

Reply Brief under 37 C.F.R. §41.41 dated April 7, 2005

Responsive to Examiner's Answer dated February 9, 2005

drugs. Therefore, the motivation can be implicit from the prior art as a whole, rather than expressly stated in the references and Choi clearly implies blood vessels can be one possible treatment site in which a device, i.e. stent-graft is used to correct for failure of blood flow.

5 ...In conclusion, to provide a *drug* delivery device is an obvious expedient to one of ordinary skill in the art and one of ordinary skill in the art would look for ways to accomplish that. Using a drug containing coating clearly accomplishes that objective.

10 By the Examiner's own admission, all that Choi discloses is a drug containing coating and the implication of a blood vessel as a treatment site. From there the Examiner conveniently uses "an obvious expedient", whatever that may be, to make the imaginary leap of putting Choi's coating on Myers' graft. Using the Examiners's logic, "an obvious expedient" can be fabricated to make every invention obvious. Choi does not once mention either the term "stent" or the term "graft," and, therefore, does not suggest coating a wall surface of a cylindrical stent having a
15 plurality of lateral openings with a bio-erodible polymer. Choi merely teaches that the erodible polymers disclosed therein "can be made into" implantable devices (see Choi, col. 28, ll. 15-17). This is too general for the "clear and particular" standard required by the Federal Circuit.

20 Moreover, claim 103 also specifies a sintered PTFE tape wound around the outer surface of the stent to form a tubular outer layer. The Examiner's general proposition that because Choi teaches a bio-erodible polymer, one of skill in the art would be motivated to coat the stent of Myers around which a PTFE tape is then wound is nothing but a hindsight reconstruction of the claim. It is important to recall the Federal Circuit's admonition in In re Dembiczak:

25 Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

Application No.: 09/997,829
Filing Date: November 29, 2001
Reply Brief under 37 C.F.R. §41.41 dated April 7, 2005
Responsive to Examiner's Answer dated February 9, 2005

There is simply no clear, particular suggestion or motivation in the prior art, explicitly or implicitly, to make the specific combination of a stent, a polymer-therapeutic substance coating on the stent and a PTFE tape wrapped on the outside of the stent as recited in the pending claims.

To say that Choi's general teaching of a bio-erodable polymer would be combined by one of skill in the art with the stent of Myers, a reference that does not mention the need for therapeutic drug incorporation, is without the requisite basis. Indeed, the Examiner's view of the applicability of Choi to implants in general is without boundary, because the same logic could be used to combine Choi with stents other than that disclosed in Myers. This appears to be a classic case of taking "the inventor's disclosure as a blueprint."

For the foregoing reasons, the Examiner's rejection should be overturned and the pending claims allowed to issue.

Date:

April 7, 2005

Respectfully submitted,

Guy Cumberbatch
Guy Cumberbatch, Reg. No. 36,114
Telephone: (773) 857-7634
c/o Rajiv Yadav, Ph.D., Esq.
Registration No. 43,999
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6801
Facsimile: (949) 250-6850
Customer No.: 30452

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.